

AMENDMENTS TO THE CLAIMS

1. (Original) A container comprising:
a body; and
a lid for closing the container to hermetically seal a product therein, said lid having a sealing rim including a layer of elastomeric material which sealingly engages with a sealing rim of the container body, and said elastomeric sealing material extending into the interior of the container beneath the lid to provide an elastomeric formation operative to engage an upper surface of the product within the container so as to apply a resilient bias thereto to hold a lower face of the product against the base of the container.
2. (Original) A container according to claim 1, wherein the sealing engagement provides a first, static, seal and a second, dynamic, seal.
3. (Original) A container according to claim 2, wherein the static seal provides a locking action to releasably lock the lid to the sealing rim of the container body.
4. (Original) A container according to claim 1, wherein the sealing rim of the lid is of inverted channel section to which the layer of elastomeric material is applied, the elastomeric layer including a formation which engages against a formation on the sealing rim of the container body to provide therewith a static seal and the elastomeric layer also having a lip to slidably engage a surface of the sealing rim of the container to provide a dynamic seal.
5. (Original) A container according to claim 4, wherein the lip forming the dynamic seal slidably engages an inner surface of the sealing rim of the container body.
6. (Original) A container according to claim 5, wherein the formation providing the static seal is an inwardly directed lip lockably and sealingly engageable with an outwardly directed lip on the sealing rim of the container body.
7. (Original) A container according to claim 4, wherein a further sealing zone is formed between an upper end edge of the sealing rim of the container body and the immediately adjacent part of the elastomeric layer.
8. (Original) A container according to claim 1, wherein the container body has a lateral flange extending outwardly from its peripheral wall beneath the sealing rim and the flange is bordered externally over at least a substantial part of its periphery by an upstanding outer rim, said flange serving to stiffen the sealing rim to inhibit deformation thereof and degradation of the

Appl. No. : **10/612,766**
Filed : **July 2, 2003**

sealing effect, and said outer rim acting to shield the outer edge portion of the lid when it is in its fully closed position against accidental opening of the container.

9. (Original) A container according to claim 1, wherein the container is of approximately rectangular shape and opening of the container is effected by a set of first and second co-operating lugs at one of the corner portions of the container, the first lug forming part of the lid and the second lug forming part of the container body with the two cooperating lugs being side by side such that opening can be effected by lifting the first lug while pushing down on the second lug.

10. (Original) A container according to claim 1 having a facility to effect pressure relief within the interior of the container when hermetically sealed whereby to compensate for pressure variation over a temperature range to embrace sterilisation temperatures and freezing temperatures.

11. (Original) A container according to claim 1 for containing a product which is at least partially manufactured within the container by being subject at least to freeze drying within the container, wherein to facilitate freeze drying the lid is able to be applied to the container body but not fully sealed thereto to thereby permit the withdrawal of moisture during freeze drying.

12. (Original) A container according to claim 11, wherein the container includes means for releasably locking the lid in a first position with its sealing rim raised from the sealing rim of the container body sufficient to enable withdrawal of moisture from the interior of the container during freeze drying.

13. (Original) A container according to claim 12, wherein in said first position the sealing rim of the lid is uniformly spaced above the sealing rim of the container body such that after freeze drying has been completed the lid can be pushed downwardly to release the locking force and to move its sealing rim downwardly into sealing engagement with the sealing rim of the body, or the container body is able to be moved upwardly relative to the lid to achieve that effect.

Appl. No. : 10/612,766
Filed : July 2, 2003

14. (Original) A container according to claim 13, wherein the lid is releasably retained in its freeze drying position by releasable locking lugs such that upon release of the locking effect provided thereby, the lugs also act to guide the lid into its hermetically sealed position.

15. (Original) A container according to claim 11, wherein to facilitate freeze drying, the lid has a part in sealing relation to the body with another part of the lid being in a position to permit escape of moisture, and when drying is complete that latter part can then be moved into a position in which the container is hermetically sealed.

16. (Original) A container according to claim 11, wherein to provide effective heat transfer during freeze drying the outer surface of the container base is substantially planar to achieve large area surface contact with the surface of a freezing shelf of a freeze drier.

17. (Original) A container comprising:

a body; and

a lid for closing the container to hermetically seal a product therein, said lid having a sealing rim including a layer of elastomeric material which sealingly engages with a sealing rim of the container body, the sealing engagement providing a first, static, seal and a second, dynamic, seal and said elastomeric sealing material extending into the interior of the container beneath the lid to provide an elastomeric formation operative to engage an upper surface of the product within the container so as to apply a resilient bias thereto to hold a lower face of the product against the base of the container, wherein the elastomeric formation acts to inhibit movement of the product within the container, and the elastomeric formation flexes to accommodate a range of product thicknesses and/or surface irregularities.

18. (Original) A container according to claim 17, wherein the elastomeric formation is annular.

19. (Original) A container according to claim 17, wherein the container body has a lateral flange extending outwardly from its peripheral wall beneath the sealing rim and the flange is bordered externally over at least a substantial part of its periphery by an upstanding outer rim, said flange serving to stiffen the sealing rim to inhibit deformation thereof and

degradation of the sealing effect, and said outer rim acting to shield the outer edge portion of the lid when it is in its fully closed position against accidental opening of the container.

20. (Original) A container according to claim 17, having a facility to effect pressure relief within the interior of the container when hermetically sealed whereby to compensate for pressure variation over a temperature range to embrace sterilisation temperatures and freezing temperatures, wherein the pressure relief facility is provided by a deformable wall portion of at least one of the body and lid.

21. (Original) A container according to claim 20, wherein the deformable wall portion is provided in the lid and comprises a bellows-like flexible wall structure in the lid.

22. (Original) A container for a pharmaceutical product to protect the product against physical damage, said container comprising a body for housing the product and a lid for closing the container to provide a hermetically sealed enclosure for the product therein, said container having a facility for providing internal pressure relief over a range of temperatures encompassing freezing to sterilizing to permit maintenance of the hermetic seal throughout the freezing to sterilizing temperatures to which the container will be exposed.

23. (Original) A container according to claim 22, wherein the pressure relief facility is provided by a deformable wall portion at least one of the container body and lid.

24. (Original) A container according to claim 23, wherein the deformable wall portion is provided in the lid and comprises a bellows flexible wall structure in the lid.

25. (Original) A container according to claim 23, wherein the range over which the pressure relief facility is effective includes 150°C.

26. (Original) A container according to claim 22, wherein the body and lid comprise a robust semi-rigid polymer of pharmaceutical grade and the hermetic seal between co-operating parts of the body and lid is formed by an elastomeric layer therebetween.

27. (Original) A container according to claim 26, wherein the elastomeric layer is applied to a peripheral rim of the lid to sealingly co-operate with a peripheral sealing rim of the body.

28. (Original) A container according to claim 27, wherein the sealing co-operation between the elastomeric layer and the sealing rim of the body provides a first, static, seal and a second, dynamic, seal.

Appl. No. : **10/612,766**
Filed : **July 2, 2003**

29. (Original) A container according to claim 28, wherein the static seal provides a locking action to releasably lock the lid to the sealing rim of the container body.

30. (Original) A container according to claim 28, wherein the elastomeric sealing layer applied to the lid extends inwardly of the sealing zone into the interior of the container beneath the lid to provide a resilient formation to engage the product within the container and apply a resilient bias thereto in a direction towards an opposing base of the container so as to urge the product against the base and thereby to maintain the product against movement within the container.

31. (Original) A container according to claim 30, wherein the resilient formation acts to inhibit movement of the product within the container, and the resilient formation flexes to accommodate at least one of a range of product thicknesses and surface irregularities.

32. (Original) A container according to claim 31, wherein the resilient formation is annular.

33. (Original) A container according to claim 27 for containing a product which is at least partially manufactured within the container by being subject at least to freeze drying within the container, wherein to facilitate freeze drying the lid is able to be applied to the container body but not fully sealed thereto to thereby permit the withdrawal of moisture during freeze drying.

34. (Original) A container according to claim 33, wherein the container includes means for releasably locking the lid in a first position with its sealing rim raised from the sealing rim of the container body sufficient to enable withdrawal of moisture from the interior of the container during freeze drying.

35. (Original) A container according to claim 34, wherein in said first position the sealing rim of the lid is uniformly spaced above the sealing rim of the container body such that after freeze drying has been completed the lid can be pushed downwardly to release the locking force and to move its sealing rim downwardly into sealing engagement with the sealing rim of the body, or the container body is able to be moved upwardly relative to the lid to achieve that effect.

Appl. No. : **10/612,766**
Filed : **July 2, 2003**

36. (Original) A container according to claim 35, wherein the lid is releasably retained in its freeze drying position by releasable locking lugs such that upon release of the locking effect provided thereby, the lugs also act to guide the lid into its hermetically sealed position.

37. (Original) A container according to claim 33, wherein to facilitate freeze drying, the lid has a part in sealing relation to the body with another part of the lid being in a position to permit escape of moisture, and when drying is complete that latter part can then be moved into a position in which the container is hermetically sealed.

38. (Original) A container according to claim 33, wherein to provide effective heat transfer during freeze drying the outer surface of the container base is substantially planar to achieve large area surface contact with the surface of a freezing shelf of a freeze drier.

39. (Original) A container according to claim 22, wherein the container is of approximately rectangular shape and opening of the container is effected by a set of co-operating first and second lugs at one of the corner portions of the container, the first lug forming part of the lid and the second lug forming part of the container body with the two lugs being side by side such that opening can be effected by lifting the first lug while pushing down on the second lug.

40. (Original) A container according to claim 39, wherein a second set of co-operating first and second lugs is also provided at the diagonally opposite corner portion.

41. (Original) A container according to claim 27, wherein the sealing rim of the lid is of inverted channel section to which the layer of elastomeric material is applied, the elastomeric layer including a formation which engages against a formation on the sealing rim of the container body to provide therewith a static seal and the elastomeric layer also having a lip to slidably engage a surface of the sealing rim of the container body to provide a dynamic seal.

42. (Original) A container according to claim 41, wherein the lip forming the dynamic seal slidably engages an inner surface of the sealing rim of the container body.

43. (Original) A container according to claim 42, wherein the formation providing the static seal is an inwardly directed lip lockably and sealingly engageable with an outwardly directed lip on the sealing rim of the container body.

Appl. No. : **10/612,766**
Filed : **July 2, 2003**

44. (Original) A container according to 43, wherein a further sealing zone is formed between an upper end edge of the sealing rim of the container body and the immediately adjacent part of the elastomeric layer.

45. (Original) A container according to claim 27, wherein the container body has a lateral flange extending outwardly from its peripheral wall beneath the sealing rim and the flange is bordered externally over at least a substantial part of its periphery by an upstanding outer rim, said flange serving to stiffen the sealing rim to inhibit deformation thereof and degradation of the sealing effect, and said outer rim acting to shield the outer edge portion of the lid when it is in its fully closed position against accidental opening of the container.

46. (Withdrawn) A container for use in the manufacture and subsequent packaging of a haemostatic bandage, said container comprising a body and a lid applicable to the body to hermetically seal the bandage therein, said body forming a mould for manufacture of the bandage by a deposition process into the body, with the product being freeze dried within the body prior to hermetically sealed closure of the container by the lid, wherein the container includes a retention system for releasably locking the lid in a freeze drying position in which the lid is closely adjacent to the body but is spaced from its hermetically sealed position such that moisture can escape between the container body and lid for freeze drying purposes and when freeze drying is complete, the lid can be moved into its hermetically sealed position.

47. (Withdrawn) A container according to claim 46, wherein the lid assumes the same orientation relative to the container body in its freeze drying position and its hermetically sealed position whereby movement from the freeze drying position to the hermetically sealed position involves a rectilinear movement of the lid relative to the container body.

48. (Withdrawn) A container according to claim 47, wherein the lid is releasably retained in its freeze drying position by releasable locking lugs, and upon release of the locking effect provided thereby, the lugs act to guide the lid into its hermetically sealed position.

49. (Withdrawn) A container according to claim 48, wherein the lugs depend downwardly from the lid for co-operation with a locking formation on the container body, the locking formation including a slot within which a lower end portion of each respective locking lug is received and through which the locking lug moves downwardly when the lid is moved from its freeze drying position into its hermetically sealed position, thereby guiding the lid.

Appl. No. : **10/612,766**
Filed : **July 2, 2003**

50. (Withdrawn) A container according to claim 46, wherein the hermetic seal is provided by engagement of a peripheral sealing rim on the lid with a peripheral sealing rim of the body and the container body has a lateral flange extending outwardly from its peripheral wall beneath the sealing rim and the flange is bordered externally over at least a substantial part of its periphery by an upstanding outer rim, said flange serving to stiffen the sealing rim to inhibit deformation thereof and degradation of the sealing effect, and said outer rim acting to shield the outer edge portion of the lid when it is in its fully closed position against accidental opening of the container.

51. (Withdrawn) A container according to claim 49, wherein the hermetic seal is provided by engagement of a peripheral sealing rim on the lid with a peripheral sealing rim of the body and the container body has a lateral flange extending outwardly from its peripheral wall beneath the sealing rim and the flange is bordered externally over at least a substantial part of its periphery by an upstanding outer rim, said flange serving to stiffen the sealing rim to inhibit deformation thereof and degradation of the sealing effect, and said outer rim acting to shield the outer edge portion of the lid when it is in its fully closed position against accidental opening of the container, and the slots are formed within the lateral flange.

52. (Withdrawn) A container according to claim 46, wherein the container includes a facility to effect pressure relief within the interior of the container when hermetically sealed to compensate for pressure variation which will arise over a range of operating temperatures including temperatures encountered on freeze drying.

53. (Withdrawn) A container according to claim 52, wherein the pressure relief facility is provided by a deformable wall portion of at least one the body and lid.

54. (Withdrawn) A container according to claim 46, wherein the body and lid comprise a robust semi-rigid polymer of pharmaceutical grade and the hermetic seal between co-operating parts of the body and lid is formed by an elastomeric layer therebetween.

55. (Withdrawn) A container according to claim 54, wherein the elastomeric layer is applied to a peripheral rim of the lid to sealingly co-operate with a peripheral sealing rim of the body.

Appl. No. : 10/612,766
Filed : July 2, 2003

56. (Withdrawn) A container according to claim 55, wherein the sealing cooperation between the elastomeric layer and the sealing rim of the body provides a first, static, seal and a second, dynamic, seal.

57. (Withdrawn) A container according to claim 56, wherein the static seal provides a locking action to releasably lock the lid to the sealing rim of the body.

58. (Withdrawn) A container according to claim 57, wherein the elastomeric sealing layer applied to the lid extends inwardly of the sealing zone into the interior of the container beneath the lid to provide a resilient formation to engage the product within the container and apply a resilient bias thereto in a direction towards an opposing base of the container so as to urge the product against the base and thereby to maintain the product against substantial movement within the container.

59. (Withdrawn) A method of manufacturing a haemostatic bandage comprising providing a container body which acts as a mould, forming the bandage within the mould by a deposition process, applying to the container body a lid in a first configuration in which moisture can escape between the container body and lid, freeze drying the product in the container body with the lid in the first configuration, and moving the lid or a part thereof into a second configuration in which the lid is hermetically sealed to the body so that the freeze dried product is hermetically sealed within the container.

60. (Withdrawn) A method according to claim 59, wherein the first configuration of the lid is a first position of the lid relative to the container body and the second configuration of the lid is a second position of the lid relative to the container body.

61. (Withdrawn) A method according to claim 60, wherein in the first position the lid is releasably locked relative to the container body in the same orientation it assumes when its second position such that movement of the lid from its first position to its second position is a rectilinear movement relative to the container body in a downwards direction.

62. (Withdrawn) A method according to claim 59, wherein in the first configuration a part of the lid is in sealing relation to the body with another part of the lid being in a position to permit escape of moisture, and in the second configuration the said part is moved into a position in which the container is hermetically sealed.

Appl. No. : **10/612,766**
Filed : **July 2, 2003**

63. (Withdrawn) A method according to claim 62, wherein said part of the lid is integrally hinged to the remainder of the lid and which is held in a raised position during freeze drying to permit escape of moisture, and when freeze drying is complete the hinged part can be lowered to complete the hermetically sealed closure.